



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

| SERIAL NUMBER | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|---------------|-------------|----------------------|---------------------|
|---------------|-------------|----------------------|---------------------|

08/463,904 06/05/95 PHIPPS

J ARC-2399

EXAMINER

BUCKELMAN, M

D BYRON MILLER
ALZA CORPORATION
950 PAGE MILL ROAD
PALO ALTO CA 94303-0802

33MJ/0705

ART UNIT PAPER NUMBER

5

3306

DATE MAILED:

07/05/96

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

This application has been examined Responsive to communication filed on 11-6-95 This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), 0 days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- Notice of References Cited by Examiner, PTO-892.
- Notice of Draftsman's Patent Drawing Review, PTO-948.
- Notice of Art Cited by Applicant, PTO-1449.
- Notice of Informal Patent Application, PTO-152.
- Information on How to Effect Drawing Changes, PTO-1474.
- _____

Part II SUMMARY OF ACTION

1. Claims 1-18 are pending in the application.

Of the above, claims _____ are withdrawn from consideration.

2. Claims _____ have been cancelled.

3. Claims _____ are allowed.

4. Claims 1-18 are rejected.

5. Claims _____ are objected to.

6. Claims _____ are subject to restriction or election requirement.

7. This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.

8. Formal drawings are required in response to this Office action.

9. The corrected or substitute drawings have been received on 11-6-95. Under 37 C.F.R. 1.84 these drawings are acceptable; not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).

10. The proposed additional or substitute sheet(s) of drawings, filed on _____, has (have) been approved by the examiner; disapproved by the examiner (see explanation).

11. The proposed drawing correction, filed _____, has been approved; disapproved (see explanation).

12. Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has been received not been received been filed in parent application, serial no. _____; filed on _____.

13. Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

14. Other

EXAMINER'S ACTION

PCT/US95/04497 as listed on applicant's information disclosure statement filed 9/14/1995 has not been considered as a copy of that reference was not provided.

Claims 16-18 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 16-18 are considered to be purely functional recitations and therefore are not considered as further limiting.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4, 7-18 are rejected under 35 U.S.C. § 102(e) as being anticipated by Phipps et al U.S. Patent 5,423,739.

Phipps teaches a reservoir with a little or no water (column 7 lines 57-60) and a medicament which may fentanyl or sufentanil. The examiner considers whatever amount of salt existing in the Phipps device to be sufficient to maintain whatever desired milli molarity depending upon the amount of water added and the amount of time of delivery. In regards to claims 13 and 15, the little bit of water would inherently have the molarities recited until upon further hydration. In regards to claims 1, 4, 7-9, whatever final

concentration the Phipps reservoir is diluted to does not matter. Whatever flux and concentration used, the values will have other values lower at which the flux is concentration dependent. Hence, applicant's claim language will be met.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 3-4, 5-6 are rejected under 35 U.S.C. § 103 as being unpatentable over Phipps et al '739 in view of Phipps et al 5,125,894. Applicant differs from Phipps '739 in reciting Molarities and concentrations to which Phipps is silent. However, applicant's criticality appears to be maintaining fentanyl HC1 above 6 mg/ml (see figure 2). Sufentanil is not exemplified. A 6mg/ml concentration, according to the examiners calculations is about 17mm. Applicant's recited values appear to be outside the range of demonstrated criticality. It would appear that a 5mg/ml

concentration may lead to a 20% error rate. Secondly applicant's claims only require the level be maintained substantially (?) throughout the analgesic delivery period. Since Phipps '739 teaches that high concentrations of drug may be used and that it was known to deliver fentanyl an sufentanil over the course of several days to a week, to have loaded fentanyl or sufentanil to a level of excess would have been obvious when outside of applicant's criticality. Phipps '894 teaches that it was known to maintain drug concentrations at levels where flux becomes less dependent on concentration. See Phipps '894 column 11 lines 8-16. To have maintained levels above concentration dependency would have been obvious, with applicant's specific values being routine experimentation.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 1-18 are rejected under 35 U.S.C. § 103 as being unpatentable over Weaver et al U.S. Patent 5,019,034 or Sibalis 4,878,892 in view of Levy et al. Weaver teaches the delivery of drugs by electroporation. Sibalis teaches the delivery of drugs by electroosmosis. Applicant differs in reciting the drugs fentanyl and sufentanil which are taught by Levy. To the extent applicant demonstrates any unexpected results commensurate with the scope of the claims it is considered obvious to deliver fentanyl and sufentanil by electroporation/electroosmosis in various medicament concentrations including those embraced by the claims.

Any inquiry concerning this communication should be directed to Mark Bockelman at telephone number (703) 308-2112.

Mark Bockelman
MARK BOCKELMAN
PATENT EXAMINER
GROUP 3300

M. Bockelman:lf
July 2, 1996